



EMBASSY OF THE REPUBLIC OF INDONESIA
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WASHINGTON, D.C. 20036

April 1st, 2003

BY FACSIMILE

Mr. Stuart Shapiro
FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th Street, N.W.
Room # 10235
Washington, D.C., 20503

BY FIRST CLASS MAIL

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
ATTN: Docket No. 02N-0276 & Docket No. 02N-0278

**Re: Comments on the Proposed Rules for Section 305 and Section 307
of the Public Health Security and Bioterrorism Preparedness and
Response Act of 2002**

On behalf of the Government of the Republic of Indonesia, I am pleased to submit the comments from the Indonesian Ministry of Agriculture on Bioterrorism Act 2002 as attached. In addition to the comments from the concerned Ministry, I would also like to ask your kind attention on particular issues in regard with Section 305 of the Act, as follows:

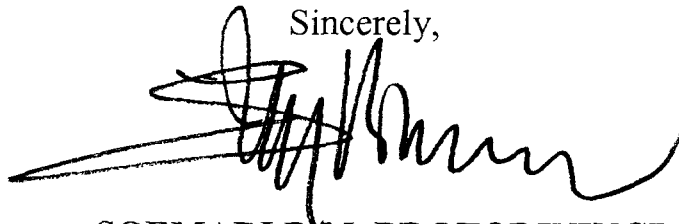
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- It is suggested that FDA will allow registration of food facilities either by electronic means (on-line registration) or by mail. To facilitate developing countries which are still lacking of internet infrastructure, registrants should also be allowed to register their facilities to FDA by facsimile. Accordingly, the registrants should receive the registration confirmations and facility's registration numbers from FDA through facsimile as well.
- It is stated that if the entry of food merchandise is not made within 6 months due to the failure of a foreign facility to register as required by Section 305, the merchandise is deemed unclaimed and abandoned and can be disposed of by the U.S. It is further suggested that before this 6 months period runs, such merchandise can be re-exported from the U.S. If the latter is the case and the merchandise which is originating from another country is to be re-exported to a third country such as Indonesia, the U.S. should promptly notify the Government of Indonesia of such a decision. The U.S. should further provide Indonesia with all information necessary for the Government of Indonesia to assess the merchandise from the health and security aspects before the merchandise is shipped to Indonesia. In other words, a third country should be given all the necessary information to allow it to assess whether the merchandise being re-exported from the U.S. poses serious health and/or security threats to the country.
- FDA is defining "port of entry" as "the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e. the port where food first arrives in the United States". It is suggested that the definition is put forth to differentiate between the port where the food physically first arrives in the U.S. and the port where the entry of the food article is processed for U.S. Customs purposes. Indonesia sees that developing two sets of definitions of "port of entry" as indicated above runs counter to the words and spirit of better facilitating flows of goods the U.S., Indonesia and other countries have been advocating in various fora. In this respect, Indonesia proposes that the clearance of imported food as required by the Act and for the purpose of the U.S. Customs be made at the port of entry where food first arrives in the U.S. Simplification such as this is necessary to avoid any bureaucratic hurdles that will only unnecessary delay the entry of food for consumption in the U.S.

I thank OMB and FDA for the opportunity to comment on the proposed rules of Section 305 and Section 307. It is our sincere wish that Indonesia's comments can be considered favorably in the context of developing free, fair and yet secure trade in food which is important not only to the U.S. but also to Indonesia.

Sincerely,

A handwritten signature in black ink, appearing to read 'Soemadi D.M. Brotodiningrat', written over a horizontal line.

SOEMADI D.M. BROTODININGRAT
AMBASSADOR

Cc

The Hon. Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drug
5600 Fisher Lane, room # HFA-305
Rockville, MD 20857

/Attachement



MENTERI PERTANIAN
REPUBLIK INDONESIA

**COMMENTS OF MINISTRY OF AGRICULTURE
ON BIOTERRORISM ACT 2002**

Regarding to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Bioterrorism Act) as signed by President George W. Bush in June 2002, the Government of Indonesia (GOI) fully understand the necessity of the Act to enable the FDA to act quickly in responding to a threatened on actual terrorist attack on the US food supply by giving the FDA information about all facilities that manufacture, process, pack or hold food for consumption in the US. Indonesia's main concern in whether or not an extra inspection (by FDA) out of the routine inspection by USA Custom would be imposed as the consequence of implementation of the Act.

Besides, the following Indonesia's concern on specific sections of the Act, is also another important concern:

1. Section 305 – (02N-0276)

- a.** Though the deadline for registration of food additives (Sept., 9, 20023) and food facilities (Dec., 12, 2003) has been set up, the registration process is not clear enough for our exporters to follow and will create difficulties for many countries including Indonesia to fully comply with the procedures as required. In this matter, the GOI needs flexibility of time to adjust and requests some supports from the US government in form of technical and financial assistance.
- b.** We believe that registration form has been available in the FDA-website and we have been informed that registration can be done through that website or faximile without any cost. In case of unsatisfisfied or rejected registration, we would like to urge FDA to inform the mentioned exporters and the government to fulfil any incomplete information before the final registration period.
- c.** We would also like to object any additional agencies in USA, which are proposed as agent for registration for foreign facilities and foreign's port authorization for our exports in order to avoid financial consequences required by the agent and the port.
- d.** In case of many facilities that belong to different companies but located in the same building or location and managed under the same procedure, we would like to propose it as a single management and therefore need only one document.

II. Section 307 - (02N-0278)

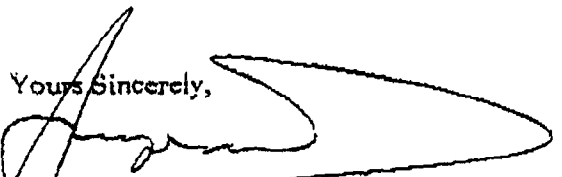
- a. We believe that the implementation of this section will give additional and time consuming task to the US importers, which may discourage them to import foods from abroad. Therefore, we propose FDA to simplify the process of prior notice of imported food shipments.
- b. In avoiding the practising of moral hazzard in the implementation of this section, in which the prior notice is not done according to the default time (no less than (8) hours and not less than (5) days until the regulation takes effect), we would like to suggest FDA to give right to our exporters to also submit the notice.

Indonesia understands the need for the Bioterrorism Act 2002. However, the Act should not impede trade between the two countries. Complicated and excessively strict inspection process would affect the competitiveness of Indonesian products and may discourage US traders from importing Indonesian products.

In this regard, my government would strongly urge the US authorities to fully consider our grave concerns in respect of this Act, which we believe would create new trade barriers for food export products from Indonesia.

My government will reserve its right to request further clarifications and explanations either through the FDA or the Committee on TBT and SPS of WTO. I hope the US will accept the assurances of my highest consideration and ensure that the implementation of the Bioterrorism Act does not create the obstacles and embarrassment for international trade for doing business between the two countries.

Yours Sincerely,



Prof. Dr. Bungaran Saragih
Minister of Agriculture, Rep of Indonesia